

F.2d 549, 551-52 (CCPA 1976) (Emphasis in original.)

Claims 1 – 11 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lokkesmoe et al. (US Patent 5,674,538) and Huber, (US Patent 4,013,581), which the Examiner asserts embraces the claimed invention. Applicant respectfully disagrees.

Applicant claims a method for preparing a sterilizing solution comprising storing a solid material comprising dipercarboxylic acid and dissolving the dry solid material into water to provide the sterilizing solution. As Applicant states in the specification, a need exists for compositions and methods that provide effective sterilizing solutions without concerns for stability and shelf life, or transportation of hazardous and bulky solutions. Applicant's invention solves this long-sought need by providing a method of using dipercarboxylic acids in solid form for use at a later time as a solute in an aqueous sterilization solution. Applicant claims a sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation. (See claim 1.)

As stated in the MPEP, § 2143, in presenting a *prima facie* case of obviousness, the Examiner has the burden of meeting three basic criteria. First, there must be some suggestion or motivation in the references or within the knowledge of one having ordinary skill in the art, to modify the teaching of the reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. Applicant respectfully asserts that the Examiner has failed to present a *prima facie* case of obviousness.

First, the prior art references presented by the Examiner do not teach or suggest all the claim limitations. Applicant claims a sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation. Lokkesmoe teaches that small concentrations of percarboxylic acid may be used as an "antimicrobial agent." The examples, claims and discussion of Lokkesmoe all teach that the "antimicrobial agent" is applied at percarboxylic acid concentrations ranging from about 5 to 100 ppm. (Lokkesmoe, see for example claim 1 and Tables 2 and 3 at column 10.) Likewise, the secondary reference presented by the Examiner, U.S. Patent 4,013,581 of Huber, discloses a bleach tablet made of a dipercarboxylic acid that dissolves in water to form a concentration of about 5 ppm to about 200 ppm. (Column 5, lines 10-11.) There is no teaching or suggestion in the Huber reference that the bleach tablet may dissolve in quantities sufficient to comprise a sterilizing solution having a dipercarboxylic acid concentration in excess of 0.1 wt%.

As disclosed by Applicant, “The select subset of dipercarboxylic acids of the present invention are unique sterilizing agents in that they can form dry solid particulates, yet they can still be readily dissolved in water with minimal agitation, such as stirring.” (*Spec.*, page 7, lines 1-3.) What has not been known in the art is that there is a subset of dipercarboxylic acids that may be dissolved in water in sufficient quantity to form a sterilizing solution *and* that may be stored as a solid until needed as a sterilizing solution. Dipercarboxylic acids that are of lower molecular weight cannot be stored as a solid under ambient conditions. Dipercarboxylic acids that are of higher molecular weight are not sufficiently soluble in water to form an aqueous solution having adequate sterilization properties.

Applicant has therefore claimed, and limited the claims, to dipercarboxylic acids that may be formed into a solid and then dissolved in water to form at least a 0.1 wt% solution that may be used for a sterilizing solution, such as for sterilizing surgical instruments in a non-hospital environment.

Neither of the references presented by the Examiner teach or suggest that the dipercarboxylic acids may be formed into a solid and used in a sterilizing solution at a concentration ranging from 0.1 weight percent to saturation. Because neither of these references teach or suggest Applicant’s claimed sterilizing solution having Applicant’s claimed concentration limitation, Applicant respectfully asserts that the Examiner has failed to present a *prima facie* case of obviousness by failing to present references that teach or suggest all of Applicant’s claimed limitations. Reconsideration and withdrawal of the rejection is requested.

Secondly, the references cited by the Examiner to support the §103(a) rejection neither teach nor suggest, as required in a *prima facie* case of obviousness, that there may be an expectation of success in forming a solid dipercarboxylic acid that may be dissolved in water at sufficient concentration to form a sterilizing solution having at least 0.1 wt % dipercarboxylic acid. Huber teaches that sufficient quantity of a solid dipercarboxylic acid may be dissolved to form a bleach solution having a concentration of between about 5 to 200 ppm. There are only a few dipercarboxylic acids that may be stored as a solid and dissolved in sufficient quantity to form a sterilizing solution. Huber does not teach or suggest that any dipercarboxylic acid may be dissolved in water at sufficient quantity to provide a sterilizing solution. Neither of the references presented by the Examiner demonstrate any likelihood of success in combining the references.

As pointed out by Applicant, the prevailing thought in the art of sterilants was that

dipercarboxylic acids having a molecular weight high enough to make into a solid were not soluble enough to be useful as a sterilizing agent. (*Spec.*, page 2, lines 19-28.) Eggensperger even asserts, albeit wrongly, that diperadic acid cannot be sufficiently solubilized to form a sterilizing agent. (U.S. Patent 4,129,517, column 1, lines 39-41.) Such was the state of the art at the time of Applicant's invention. None of the references that the Examiner has presented contradicts Appellant's observation. None of the references presented by the Examiner teach or suggest that there are dipercarboxylic acids that may be formed in a solid form and then solubilized in sufficient concentration to form a sterilizing solution. None of the references presented by the Examiner teach or suggest a likelihood of success of forming a solid dipercarboxylic acid that may then be dissolved in water to form a 0.1 weight percent sterilizing agent. Applicant asserts that having failed to present references that teach or suggest a likelihood of success in forming a solid dipercarboxylic acid that may be dissolved to form a 0.1 weight percent solution in water, the Examiner has failed to present a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection is respectfully requested.

Thirdly, neither of the references cited by the Examiner disclose that a dipercarboxylic acid may be used as a sterilizing agent in an aqueous solution that is essentially free of hydrogen peroxide, as claimed by Applicant in claim 6. To present a *prima facie* case of obviousness, the Examiner must present references that teach or suggest all the claimed limitations of the invention being examined. Applicant asserts that by not presenting references that teach or suggest the use of dipercarboxylic acids in an aqueous solution as a sterilizing agent without the addition of peroxide, the Examiner has not presented a *prima facie* case of obviousness.

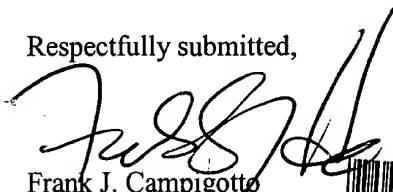
Lokkesmoe teaches that, "The carboxylic acid constituent within the present composition when combined with aqueous hydrogen peroxide generally functions as an antimicrobial agent as a result of the presence of the active hydrogen atom. (Column 4, lines 45-48.) The examples Lokkesmoe provides are based upon a "POAA" formula set forth in Working Example 1 and showing a composition of, *inter alia*, acetic acid and hydrogen peroxide. (Column 9, lines 15-20). Even when Lokkesmoe uses different acids, there is still hydrogen peroxide present. (Working Example 9.) Therefore, while Lokkesmoe teaches that percarboxylic acids may be used in combination with hydrogen peroxide to form a composition for controlling microbial growth, Lokkesmoe does not teach or suggest that dipercarboxylic acid *alone* is an effective composition for

use as a *sterilizing* agent when dissolved in water. Applicant's claim 6 specifically claims a sterilizing solution that is substantially free of hydrogen peroxide.

The Examiner states, "Lokkesmoe teaches a method of controlling microbial growth in aqueous stream by using percarboxylic acid." (*O.A.*, page 3, lines 15-16.) However, as discussed above, Lokkesmoe teaches a method of using a percarboxylic acid *with hydrogen peroxide*. Applicant claims using a dipercarboxylic acid without hydrogen peroxide as a necessary ingredient. Referring to Applicant's claim 6, Applicant specifically excludes hydrogen peroxide as a component of the sterilizing solution. Because the Examiner has not presented references that teach or suggest each of Applicant's claimed limitation, reconsideration and withdrawal of the rejection of claim 6 is requested.

Pursuant to the preceding remarks and amendments, Applicant reasserts that all the claims are now in condition for allowance. Applicant therefore requests that a Notice of Allowance be issued for this patent application. In the event there are additional charges in connection with the filing of this Response, the Commissioner is hereby authorized to charge the Deposit Account No. 50-0714/LYNN/0120 of the firm of the below-signed attorney in the amount of any necessary fee.

Respectfully submitted,

  
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